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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,362	01/14/2002	Sau Lan Tang Staats	PST-104US	2899

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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/046,362	STAATS, SAU LAN TANG
	Examiner	Art Unit
	Brian R. Gordon	1743

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *9-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *4-15-02* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9-24-02; 4-15-02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, 1-8, and 25, in the reply filed on September 10, 2004 is acknowledged.

2. Claims 9-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 10, 2004.

Claim Interpretation

3. Claims 1, 5, 6, and 25 are described as device/apparatus claims in the preamble; however, each of the claims contains clauses directed to the process by which the devices/apparatuses are made. The process limitations have not been searched. In an apparatus claim, the process by which the apparatus is formed is not considered to further limit the structure of the apparatus. As such claims 1 and 6 are interpreted as a device comprising a substrate, a channel on the substrate, and the channel having a side wall comprising polymeric material. Claim 25 is interpreted as a structure comprising a substrate and a channel where in the channel comprises a bottom and a sidewall. If applicant desires to claim the process, claim 25 should be amended to recite a method or process of forming/manufacturing a microfluidic device comprising a substrate including a channel with a bottom and a sidewall therein, said method/process comprising the steps of.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the base and overhang must be shown (and labeled) or the feature(s) canceled from the claim(s). No new matter should be entered.

It is unclear what applicant considers as the overhang, base, and extension within the Figures. Clarification is requested.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claims 1 and 6 are objected to because of the following informalities: The claims are essentially duplicate claims. The only difference is the preamble. Structurally, the devices of claims 1 and 6 are equivalent. Applicant has merely chosen to refer to the combination of elements by different names. One of the claims should be canceled or amended to include additional structure to provide a basis differentiation between the two apparatuses. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 4, 5, 7, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 4 it is unclear how the overhang is connected/related to the other elements of the microfluidic device. Is the base on the substrate? Is the base connected to the channel?

As to claim 5, it appears as if the claim is directed to the polymer material of the process clause rather than the polymer material of the side wall. Claim 5 does not further limit the structure of the device. As such any device in which the side wall comprises polymeric material meets the limitation of the claim.

As to claim 25, it is unclear if applicant intends to claim a process or structure. For the purpose of examination the claim has been treated as a structure as interpreted above.

Unless applicant can show the claimed process results in a structure different from that of the prior art, the devices are considered structurally equivalent.

As to claim 7, it is unclear how a master mold can contain channels (which would be a negative reflection) and a positive reflection. Generally it is known for a mold to have opposing molds a negative reflection which mates with a corresponding positive reflection to form a mold.

8. Claim 5 recites the limitation "the microdroplets" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-3, 5-7, and 25 rejected under 35 U.S.C. 102(e) as being anticipated by Parce et al. US 6,787,088.

Parce et al. disclose microfluidic devices for the performance of chemical and biochemical analyzes, syntheses and detection. The devices of the invention combine

precise fluidic control systems with microfabricated polymeric substrates to provide accurate, low cost miniaturized analytical devices that have broad applications in the fields of chemistry, biochemistry, biotechnology, molecular biology and numerous other fields.

The invention also provides a method of fabricating microfluidic devices for use with an electroosmotic fluid direction system. The method comprises molding a polymeric material to form a substrate that has at least one surface, and at least first and second intersecting channels disposed in that surface. Each of the at least first and second intersecting channels has an interior surface which has a surface potential associated therewith, which is capable of supporting sufficient electroosmotic flow of a fluid in those channels. Again, at least one of the intersecting channels has at least one cross-sectional dimension in the range of from about 0.1 μm to about 500 μm. A cover layer is overlaid on the surface of the substrate, whereby the cover layer encloses the intersecting channels. Together, the substrate and cover layer will also comprise at least three ports disposed therein, each of the at least three ports being in fluid communication with first and second termini of said first channel and at least one terminus of the second channel.

Typically, the polymeric substrates used in the devices of the invention are fabricated in two or more parts. Specifically, a first planar substrate element is provided having a plurality of grooves and/or wells, corresponding to the fluid channels and/or chambers, manufactured, e.g., molded or machined, into one of its planar surfaces. These grooves provide the bottom (claim 3) and side walls of the channels and

chambers of the devices. A second planar substrate element (cover as in claim 2) is then mated with the first to define the top wall of the channels and chambers. The two members are bonded together in order to ensure that the channels and chambers in the substrate are fluid tight. Bonding of the two members may be accomplished by a number of methods that are known in the art, such as through the use of adhesives, e.g., UV curable adhesives, or by sonically welding one member to the other.

11. Claims 6-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al. US 6,645,432.

Anderson et al. discloses a variety of methods providing relatively simple and low cost fabrication techniques for producing the inventive microfluidic structures described herein. The preferred methods provided according to the invention and described below are based upon utilizing a hardenable liquid to create replica molded structures that comprise, or are assembled with other replica molded structures to form, the three-dimensional microfluidic network structures provided by the invention.

Mold master 300, having positive, high-relief topological features 302 formed on a surface 304 thereof comprises, in some preferred embodiments, a substrate that has been modified, for example, via photolithography or any suitable micromachining method apparent to those of ordinary skill in the art. Topological features 302 are shaped, sized, and positioned to correspond to a desired arrangement of channels in the level of the overall microfluidic network structure being formed by the mold master. In one preferred embodiment, mold master 300 comprises a silicon wafer having a surface 304 that has been via photolithography utilizing a photomask having a pattern

therewithin corresponding to a desired pattern of topological features 302. Techniques for forming positive (claim 7) relief patterns of topological features on silicon, or other materials, utilizing photolithography and photomasks, are well known and understood by those of ordinary skill in the art.

In a particularly preferred embodiment, mold master 300 comprises a silicon or other substrate, which has been spincoated with one or more layers of a commercially available polymeric photoresist material. In such preferred embodiments, topological features 302 can be easily, conveniently, and accurately formed in the layer(s) of photoresist forming surface 304 of substrate 300 via exposure of photoresist to radiation through a photomask and subsequent development of the photoresist material to remove photoresist material from the surface and regions surrounding features 302 thus leaving behind topological features 302 in positive relief. A variety of positive and negative photoresists (claims 7 and 8) can be utilized for such purposes and are well known to those of ordinary skill in the art.

Mold master 306 can be comprised of the same material as mold master 300; however, in preferred embodiments, mold master 306 is formed of an elastomeric material, for example, an elastomeric polymer.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. He, Lin et al.; Strand, David et al.; Staats, Sau Lan Tang; Parce; John Wallace et al.; Quake, Stephen R. et al.; Sundberg, Steven A. et al.; Robotti, Karla M. et al.; Chazan, David et al.; Wolk, Jeffrey A. et al.; Bentsen; James G. et al.; Chazan;

David; Griffiths; Stewart K. et al.; Anderson; Janelle R. et al.; Hu; Xiaowen et al.; Dapprich; Johannes; O'Connor; Stephen D. et al.; Kennedy; Colin B.; and Kopf-Sill Anne R. et al. disclose microfluidic devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

brg

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